510(K) SUMMARY K081160 (1/2)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

JUN 24 2008

1. Submitter's Name: AViTA Corporation

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Contact: Mr. Nelson Lin / R&D Manager

2. Device Name :

Trade Name: AViTA Radar Thermo IR Thermometer,
Model no.: NT1 Series

Common Name: IR Thermometer

Classification name thermometer, electronic, clinical

3. DEVICE CLASS The **AViTA Radar Thermo IR Thermometer, (Model no.: NT1 Series)** has been classified as

Regulatory Class: II
Panel: 80
Product Code: FLL
Regulation Number: 21CFR 880.2910

4. Predicate Device: The predicate device is the **Thermofocus 01500 Series Thermometer (K033790)** marketed by **TECNIMED S,R.L.**.

5. Intended Use: **AViTA Radar Thermo NT1 Series IR Forehead Thermometer** is an infrared thermometers intended for the intermittent measurement of human body temperature in people of all ages.

6. Device Description: **AViTA Radar Thermo NT1 Series IR Thermometer** is hand-held and battery-operated, taking skin temperature mainly in the middle of the forehead. The **AViTA Radar Thermo NT1 Series IR Thermometer** uses the principle of surveying the natural emission of infrared thermal radiation from all objects, including the human body.

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Making use of an **IR Emitter/Deector Operation Distance Detecting System**, the **AViTA Radar Thermo NT1 Series IR Thermometer** takes the temperature at distance, without any contact with the patient.

7. Performance Summary:

In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included ASTM E1965-98(2003) , IEC 60601-1 and IEC 60601-1-2 requirements.

8. Conclusions:

The **AViTA Radar Thermo NT1 Series IR Forehead Thermometer** has the same intended use and similar technological characteristics as the **Thermofocus 01500 Series Thermometer (K033790)**marketed by **TECNIMED S,R.L.**. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, The **AViTA Radar Thermo NT1 Series IR Forehead Thermometer** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2008

AViTA Corporation
C/O Ms. Jennifer Reich
Senior Consultant
Harvest Consulting Corporation
2904 North Boldt Drive
Flagstaff, Arizona 86001

Re: K081160
Trade/Device Name: AViTA Radar Thermo IR Thermometer
Model no.: NT1 Series
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: April 15, 2008
Received: April 23, 2008

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

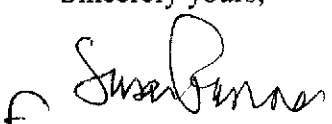
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: AViTA Radar Thermo IR Thermometer,
Model no.: NT1 Series
AViTA Corporation

Indications For Use:

The device is an infrared thermometer intended for the intermittent measurement of human body temperature in people of all ages.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___V___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081169